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10/570,598	06/28/2006	Norio Hayashi	023312-0121	9881

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EXAMINER	
HISSONG, BRUCE D	
ART UNIT	PAPER NUMBER
1646	
MAIL DATE	DELIVERY MODE
12/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/570,598	HAYASHI, NORIO	
	Examiner	Art Unit	
	Bruce D. Hissong, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *1-10 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/6/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, claim 11, and IL-15 in the reply filed on 9/12/2008 is acknowledged. The traversal is on the ground(s) that the search and examination of Groups I-III is not unduly burdensome because all of the groups are drawn to treating hepatitis C.

These arguments have been fully considered and are not persuasive. As set forth on pages 2-3 of the requirement for restriction mailed on 7/16/2008, Groups I-III do not relate to a single inventive concept under PCT Rule 13.1 because the groups lack a special technical feature under PCT Rule 13.2, and thus restriction is deemed proper. It is also noted that the composition of claim 1 could be used for purposes other than treatment of Hepatitis C. Although the claims are drawn to a pharmaceutical composition "for treating chronic hepatitic C", this limitation is merely an intended use, and the composition itself could be used for other purposes, such as in methods of treating certain types of cancer, or as an immunogen to raise antibodies specific for IL-15. Furthermore, group III is drawn to the "use of IL-15" in the manufacture of a medicine, rather than use in treating hepatitis C.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-12 are currently pending. Claims 1-10 and 12 are withdrawn as non-elected subject matter, and claim 11 is the subject of this office action.

Information Disclosure Statement

The information disclosure statement received on 3/6/2006 has been fully considered.

Claim Objections

1. Claim 11 is objected to for recitation of non-elected subject matter. Specifically, with Applicant's election of IL-15 as the active ingredient, the recitation of myeloid dendritic cell maturation factors and lectin-binding substances represents a recitation of non-elected subject matter. Applicant is required to delete non-elected subject matter upon identification of allowable subject matter.

2. The Examiner suggests amending claim 11 to recite "interleukin-15 (IL-15) in order to explicitly identify the acronym IL-15 upon its first use in a claim.

3. The Examiner suggests amending claim 11 to recite a method of treating hepatitis C, comprising "administering" to a patient, rather than "administration" since the administering is an active method step.

Specification

1. The specification is objected to for the following informalities: The specification contains numerous instances of a question mark (?) appearing where a Greek symbol seems to have been intended. For example, see p. 7, line 23. Appropriate correction is required.

2. The use of the trademarks FACScan™, RNeasy™, and TaqMan™ has been noted in this application. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Corado *et al* ("Corado" - *Clin. Exp. Immunol.*, 1997, Vol. 109, p. 451-457) in view of Fehniger *et al* ("Fehniger" - *Blood*, 2001, Vol. 97, p. 14-32), and further in view of Schlaak *et al* ("Schlaak" - *J. Acquired Immune Deficiency Syndromes,* 2002, Vol, 29, p. 145-148).

Claim 11 is drawn to a method treating chronic hepatitis C, comprising administration to a patient an effective amount of IL-15.

Corado discloses a correlation between hepatitis C virus (HCV) infection and impaired or inhibited natural killer (NK) cell activity. Specifically Corado shows that NK cells from HCV-infected individuals exhibited decreased cytotoxic activity against target cells (see Fig 2). Corado also shows that this inhibition of NK cell activity can be alleviated by exposure of NK cells to IL-2. Corado is silent regarding administration of IL-15 to patients with chronic hepatitis C.

Schlaak shows that administration of IL-2 to HCV-infected individuals was effective in improving both liver function and lowering or eliminating HCV RNA serum levels (see abstract; Fig. 1; Table 1). Schlaak is silent regarding administration of IL-15 to patients with chronic hepatitis C.

However, Fehniger discloses that the IL-15 is a cytokine which shares many properties with IL-2, such as the ability to stimulate T cell proliferation, and the use of shared receptor components, such as the IL-2Rb subunit, which transmits signals for both IL-2 and IL-15 signaling (p. 14, 1st column – 2nd column, 2nd paragraph). Fehniger also shows that IL-15 induces NK cell proliferation and cytotoxicity, as well as regulating interaction between NK cell and other cells, such as macrophages (p. 20, 1st column – p. 21, 1st column).

Therefore, one of ordinary skill in the art, at the time the instant invention was conceived, would have been motivated to practice a method of treating patients with chronic hepatitis C by administering an effective amount of IL-15. The motivation to do so comes from the combined teaches of Corado and Fehniger, which collectively show a correlation between HCV infection and decreased NK cell activity, and a cytokine, IL-15, which stimulates NK cell activity in terms of proliferation and cytotoxic activity. Thus, one of ordinary skill in the art would know that administration of IL-15 would likely increase NK cell activity in HCV-infected patients, leading to more effective viral clearance. Further motivation comes from Corado and Schlaak, which show that a cytokine, IL-2, which shares common biological activities and a common receptor signaling component with IL-15, is effective in enhancing NK cell activity in HCV-infected patients (Corado) and increasing liver function while lowering HCV RNA levels in HCV-infected patients (Schlaak). Therefore, because Corado and Fehniger provide the motivation to increase NK cell activity in HCV-infected patients by administration of IL-15, and Corado and Schlaak both show that a cytokine, IL-2, which shares many biological activities with IL-15, is also useful for treating HCV-infected patients, one of ordinary skill in the art would have both the motivation, and a reasonable expectation of success in practicing a method of treating chronic hepatitis C by administration of IL-15.

Conclusion

No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571)272-3324. The examiner can normally be reached M-F from 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bruce D. Hissong
Art Unit 1646

/Robert Landsman/
Primary Examiner, Art Unit 1647